

03/10/2004

Sheet 1 of 5

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 14539-006003	Application No. 10/800,250
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Takashi Tsuji et al.	
		Filing Date 03/10/2004 Herewith	Group Art Unit 1644

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
J0	AA	5,506,126	4/9/1996	Seed et al.			
	AB	5,521,288	5/28/1996	Linsley et al.			
	AC	5,914,112	06/22/1999	Bednar et al.			
	AD	6,075,181	6/13/2000	Kucherlapati et al.			
J0	AE	2002/0156242	10/24/2002	Tamatani et al.			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AF	WO 97/26912	07/31/1997	WIPO				
	AG	WO 98/11909	03/26/1998	WIPO				
	AH	WO 98/37415	08/27/1998	WIPO				
	AI	WO 98/38216	09/03/1998	WIPO				
	AJ	WO 98/45331	10/15/1998	WIPO				
	AK	WO 99/15553	04/01/1999	WIPO				
	AL	WO 00/19988	04/13/2000	WIPO				
	AM	WO 00/46240	08/10/2000	WIPO				
	AN	WO 00/67788	11/16/2000	WIPO				
	AO	WO 01/08700	02/08/2001	WIPO				
	AP	WO 01/12658	02/22/2001	WIPO				
	AQ	WO 01/15732	03/08/2001	WIPO				
	AR	WO 01/18022	03/15/2001	WIPO				
	AS	WO 01/21796	03/29/2001	WIPO				
	AT	WO 01/32675	05/10/2001	WIPO				
	AU	WO 01/64704	09/07/2001	WIPO				
	AV	WO 01/87981	11/22/2001	WIPO				
	AW	WO 02/44364	06/06/2002	WIPO				
	AX	WO 02/70010	09/12/2002	WIPO				

Examiner Signature <i>John A. Spensh</i>	Date Considered 10/30/2006
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		Filing Date <u>03/10/2004</u> <del>Herewith</del>	Group Art Unit <u>1644</u>

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
<del>AY</del>	<del>AZ</del>	<del>WO 02/76504</del>	<del>10/03/2002</del>	<del>WIPO</del>				
	AZ	AU 13320/99	04/12/1999	AU				
	AAA	DE 19821060	04/15/1999	DE				
	ABB	EP 0984023 A1	03/08/2000	EP				
	ACC	EP 1 125 585 A1	08/22/2001	EP				

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	ADD	Aicher et al., "Characterization of Human Inducible Costimulator Ligand Expression and Function," J. IMMUNOL., 164(9):4689-4696 (2000)
	AEE	Bajorath, "A molecular model of inducible costimulator protein and three-dimensional analysis of its relation to the CD28 family of T cell-specific costimulatory receptors," J. MOL. MODEL 5:169-176 (1999)
	AFF	Beier et al., "Induction, binding specificity and function of human ICOS," EUR. J. IMMUNOL., 30(12):3707-3717 (2000)
	AGG	Bensimon et al., "Human lupus anti-DNA autoantibodies undergo essentially primary V kappa gene rearrangements," EMBO J. 13(13):2951-62 (1994)
	AHH	Brodie et al., "LICOS, a primordial costimulatory ligand?," CURR. BIOL., 10(6):333-336 (2000)
	AIJ	Buonfiglio et al., "Characterization of a novel human surface molecule selectively expressed by mature thymocytes, activated T cells and subsets of T cell lymphomas," EUR. J. IMMUNOL., 29(9):2863-2874 (1999)
	AJJ	Buonfiglio et al., "The T cell activation molecule H4 and the CD28-like molecule ICOS are identical," EUR. J. IMMUNOL. 30(12):3463-3467 (2000)
	AKK	Cameron "Recent advances in transgenic technology" MOLECULAR BIOTECHNOLOGY 7:253-65 (1997)
	ALL	Chambers, "The expanding world of co-stimulation: the two-signal model revisited," TRENDS IN IMMUNOLOGY, 22(4):217-223 (2001)
	AMM	Cocks et al., "A novel receptor involved in T-cell activation," NATURE, 376:260-263 (1995)
	ANN	Coyle et al., "The CD28-Related Molecule ICOS Is Required for Effective T Cell-Dependent Immune Responses," IMMUNITY 13(1):95-105 (2000)
	AOO	Dong et al., "Cutting Edge: Critical Role of Inducible Costimulator in Germinal Center Reactions," J. IMMUNOL., 166(6):3659-3662 (2001)
	APP	Dong, "ICOS co-stimulatory receptor is essential for T-cell activation and function," NATURE 409(6816):97-101 (2001)
	AQQ	Goni et al., "Structural and idiotype characterization of the L chains of human IgM autoantibodies with different specificities," J. Immunol. 142(9):3158-63 (1989)

Examiner Signature <i>Ilia Anspershi</i>	Date Considered <u>10/30/2006</u>
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Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
<del>ARR</del>	<del>ARR</del>	<del>Gonzalo et al., "Cutting Edge: The Related Molecules CD28 and Inducible Costimulator Deliver Both Unique and Complementary Signals Required for Optimal T Cell Activation," J. IMMUNOL., 166(1):1-5 (2001)</del>
	ASS	Guo et al., "Stimulatory Effects of B7-Related Protein-1 on Cellular and Humoral Immune Responses in Mice," J. IMMUNOL., 166(9):5578-5584 (2001)
	ATT	Hanzawa et al., "Characteristics of a TTH1 antibody which blocks an unknown adhesion phenomenon," PROCEEDINGS OF THE JAPANESE SOCIETY FOR IMMUNOLOGY, Vol. 24, Abstract No. W17-13 (1994) [ORIGINAL JAPANESE AND ENGLISH LANGUAGE TRANSLATION]
	AUU	Heyeck et al., "Developmental regulation of a murine T-cell-specific tyrosine kinase gene, Tsk," PROC. NATL. ACAD. SCI. USA, 90:669-673 (1993)
	AVV	Houdebine "Production of pharmaceutical proteins from transgenic animals" J. BIOTECHNOL. 34:269-87 (1994)
	AWW	Hutloff et al., "ICOS is an inducible T-cell co-stimulator structurally and functionally related to CD28," NATURE, 397(6716):263-266 (1999)
	AXX	Ishikawa et al., "Prediction of the Coding Sequences of Unidentified Human Genes. X. The Complete Sequences of 100 New cDNA Clones from Brain Which Can Code for Large Proteins <i>in vitro</i> ," DNA RESEARCH, 5:169-176 (1998)
	AYY	Kappel et al. "Regulating gene expression in transgenic animals" CURRENT OPINION IN BIOTECHNOLOGY 3:548-53 (1992)
	AZZ	Kopf et al., "Inducible Costimulator Protein (ICOS) Controls T Helper Cell Subset Polarization after Virus and Parasite Infection," J. EXP. MED., 192(1):53-61 (2000)
	AAAA	Kuchroo et al., "B7-1 and B7-2 costimulatory molecules activate differentially the Th1/Th2 developmental pathways: Application to autoimmune disease therapy," CELL, 80:707-718 (1995)
	ABBB	Ling et al., "Cutting Edge: Identification of GL50, a Novel B7-Like Protein That Functionally Binds to ICOS Receptor," J. IMMUNOL., 164(4):1653-1657 (2000)
	ACCC	Mages et al., "Molecular cloning and characterization of murine ICOS and identification of B7h as ICOS ligand," EUR. J. IMMUNOL., 30(4):1040-1047 (2000)
	ADDD	Marguet et al., "cDNA Cloning for Mouse Thymocyte-activating Molecule," THE JOURNAL OF BIOLOGICAL CHEMISTRY, 267(4):2200-2208 (1992)
	AEEE	McAdam et al. (2000) "Mouse inducible costimulatory (ICOS) molecule expression is increased by CD28 costimulation and regulates development of Th2 cells," FASEB JOURNAL, 14(6):A1169
	AFFF	McAdam, "ICOS is critical for CD40-mediated antibody class switching," NATURE 409(6816):102-105 (2001)
	AGGG	McAdam, "Mouse Inducible Costimulatory Molecule (ICOS) Expression Is Enhanced by CD28 Costimulation and Regulates Differentiation of CD4 <sup>+</sup> T Cells," J. IMMUNOL., 165(9):5035-5040 (2000)
	AHHH	Mueller, "T cells: A proliferation of costimulatory molecules," CURR. BIOL. 10(6):R227-R230 (2000)
	AIII	Mullins et al. "Expression of the DBA/2J Ren-2 gene in the adrenal gland of transgenic mice" EMBO J., 8:4065-72 (1989)
	AJJJ	Mullins et al. "Fulminant hypertension in transgenic rats harbouring the mouse Ren-2 gene" NATURE, 344:541-44 (1990)

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	AKKK	Mullins et al., "Transgenesis in nonmurine species" Hypertension 22:630-33 (1993)
	ALLL	Niemann "Transgenic farm animals get off the ground" TRANSGENIC RESEARCH, 7:73-75 (1998)
	AMMM	Nojima et al., "The 4F9 antigen is a member of the tetra spans transmembrane protein family and functions as an accessory molecule in T cell activation and adhesion," CELLULAR IMMUNOLOGY, 152:249-260 (1993)
	ANNN	Overbeek "Factors affecting transgenic animal production," Transgenic Animal Technology, A Laboratory Handbook 96-98 (1994)
	AOOO	Özkaynak et al., "Importance of ICOS-B7RP-1 costimulation in acute and chronic allograft rejection," NATURE IMMUNOLOGY 2(7):591-596 (2001)
	APPP	Pech et al., "A large section of the gene locus encoding human immunoglobulin variable regions of the kappa type is duplicated," J. Mol Biol. 183(3):291-9 (1985)
	AQQQ	Poster, Kyoto International Conference Hall, Takaragaike, Sakyo-ku, Kyoto, JAPAN (November 30, 1994) [ORIGINAL JAPANESE AND ENGLISH LANGUAGE TRANSLATION]
	ARRR	Redoglia et al., "Characterization of H4: a mouse T lymphocyte activation molecule functionally associated with the CD3/T cell receptor," EUR. J. IMMUNOL., 26(11):2781-2789 (1996)
	ASSS	Riley et al., "ICOS Costimulation Requires IL-2 and Can Be Presented by CTLA-4 Engagement," J. IMMUNOL., 166(8):4943-4948 (2001)
	ATTT	Robert et al., "Antibody Cross-Linking of the Thymocyte-Specific Cell Surface Molecule CTX Causes Abnormal Mitosis and Multipolecleation of Tumor Cells," EXPERIMENTAL CELL RESEARCH, 235:227-237 (1997)
	AUUU	Sato et al. (2000) "Up-regulation of inducible co-stimulator (ICOS) expression and its regulation of cytokine production in inflammatory bowel disease," Gastroenterology, 118(4):A662
	AVVV	Sharpe, "Analysis of lymphocyte costimulation <i>in vivo</i> using transgenic and 'knockout' mice," CURRENT OPINION IN IMMUNOLOGY, 7:389-395 (1995)
	AWWW	Sigmund "Are studies in genetically altered mice out of control?" ARTERIOSCLER. THROMB. VASC. BIOL., 20:1425-29 (2000)
	AXXX	Swallow et al., "B7h, a Novel Costimulatory Homolog of B7.1 and B7.2, Is Induced by TNF $\alpha$ ," IMMUNITY, 11(4):423-432 (1999)
	AYYY	Tafari et al., "ICOS is essential for effective T-helper-cell responses," NATURE 409(6816):105-109 (2001)
	AZZZ	Tai et al., "A role for CD9 molecules in T cell activation," J. EXP. MED., 184:753-758 (1996)
	AAAAA	Tamatani et al., "AILIM/ICOS: a novel lymphocyte adhesion molecule," INTERNATIONAL IMMUNOLOGY, 12(1):51-55 (2000)
	ABBBB	Tamatani et al., "Characteristics of an antibody which induces an ICAM-1-LFA-1-independent adhesion pathway," PROCEEDINGS OF THE JAPANESE SOCIETY FOR IMMUNOLOGY, Vol. 23, Abstract No. H-160 (1993) [ORIGINAL JAPANESE AND ENGLISH LANGUAGE TRANSLATION]
	ACEEE	Tezuka et al., "Genetic cloning of a lymphocyte surface signal transduction molecule which induces an unknown adhesion phenomenon," PROCEEDINGS OF THE JAPANESE SOCIETY FOR IMMUNOLOGY, Vol. 24, Abstract No. W17-14 (1994) [ORIGINAL JAPANESE AND ENGLISH LANGUAGE TRANSLATION]

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Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	<del>ADDDD</del>	<del>Tezuka et al., "Identification and Characterization of Rat AILIM/ICOS, a Novel T-Cell Costimulatory Molecule, Related to the CD28/CTLA4 Family," BIOCHEM. BIOPHYS. RES. COMMUN., 276(1):335-345 (2000)</del>
	<del>AEEEE</del>	<del>Tomlinson et al., "The repertoire of human germline VH sequences reveals about fifty groups of VH segments with different hypervariable loops," J. Mol. Biol. 227(3):776-98 (1992)</del>
	<del>AFFFF</del>	<del>Wall "Transgenic livestock: progress and prospects for the future" THERIOGENOLOGY 45:57-68 (1996)</del>
	<del>AGGGG</del>	<del>Wang et al., "Costimulation of T cells by B7-H2, a B7-like molecule that binds ICOS," BLOOD, 96(8):2808-2813 (2000)</del>
<u>IO</u>	AHHHH	Yoshinaga et al., "Characterization of a new human B7-related protein: B7RP-1 is the ligand to the co-stimulatory protein ICOS," INTERNATIONAL IMMUNOLOGY, 12(10):1439-1447 (2000)
	<del>AIIII</del>	<del>Yoshinaga et al., "T cell co-stimulation through B7RP-1 and ICOS," NATURE, 402(6763):827-832 (1999)</del>

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Sheet 1 of 3

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	Applicant Takashi Tsuji et al.		
	Filing Date March 10, 2004	Group Art Unit 16434	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
J10	AA	5,484,892	01/16/1996	Tedder et al.			
	AB	5,747,461	05/05/1998	Markov			
	AC	5,770,197	06/23/1998	Linsley et al.			
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	AF	20020164697	11/07/2002	Coyle et al.			
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	AH	20020182667	12/05/2002	KroczeK			

Foreign Patent Documents or Published Foreign Patent Applications								
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							Yes	No
	AI	WO 95/33770	12/14/1995	WIPO				
	AJ	WO 98/19706	05/14/1998	WIPO				
	AK	JP 5-72204	03/23/1993	Japan			Abstract	
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	AO	Campbell et al., "Separable effector T cell populations specialized for B cell help or tissue inflammation," NAT IMMUNOL. 2(9):876-81 (2001)
	AP	Chapoval et al., "B7-H3: a costimulatory molecule for T cell activation and IFN-gamma production," NAT IMMUNOL. 2(3):269-74 (2001)
	AQ	Dong et al., "B7-H1, a third member of the B7 family, co-stimulates T-cell proliferation and interleukin-10 secretion," NAT. MED. 5(12):1365-9 (1999)
	AR	Eljaschewitsch et al., "Identification of a novel activation antigen on human CD4+ T cells," IMMUNOBIOLOG., 194(1-3):27 (1995)
	AS	Goding, "Monoclonal Antibodies: Principles and Practice," 2 <sup>nd</sup> Edition, Academic Press, Orlando, Florida, Chapter 8, pages 281-293 (1986)
	AT	Gonzalo et al., "ICOS is critical for T helper cell-mediated lung mucosal inflammatory responses," NAT IMMUNOL. 2(7):597-604 (2001)
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JO	AV	Hutloff et al., "Identification and initial characterization of a novel T cell-specific cell surface activation antigen," IMMUNOBIOLOGY, 197(2-4):172 (1997)
	AW	Ihara et al., "Association studies of CTLA-4, CD28, and ICOS gene polymorphisms with type 1 diabetes in the Japanese population," IMMUNOGENETICS 53(6):447-54 (2001)
	AX	Iiyama et al., "The role of inducible co-stimulator (ICOS)/B7-related protein-1 (B7RP-1) interaction in the functional development of Peyer's patches," IMMUNOLOGY LETTERS, In Press, Uncorrected Proof available online April 11, 2003, <a href="http://www.sciencedirect.com/science/journal/01652478">http://www.sciencedirect.com/science/journal/01652478</a>
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	AAA	Ling et al., "Differential expression of inducible costimulator-ligand splice variants: lymphoid regulation of mouse GL50-B and human GL50 molecules," J IMMUNOL. 166(12):7300-8 (2001)
	ABB	Linsley, "T cell activation: you can't get good help," Nat Immunol. 2(2):139-40 (2001)
	ACC	Liu et al. "B7H costimulates clonal expansion of, and cognate destruction of tumor cells by, CD8(+) T lymphocytes in vivo," J EXP MED. 194(9):1339-48 (2001)
	ADD	Lucia et al., "Expression of the novel T cell activation molecule hpH4 in HIV-infected patients: Correlation with disease status", AIDS RESEARCH AND HUMAN RETROVIRUSES 16(6):549-557 (2000)
	AEE	Mackay et al., "Follicular homing T helper (Th) cells and the Th1/Th2 paradigm," J EXP MED. 192(11):F31-4 (2000)
	AFF	Nurieva et al., "Inducible costimulator is essential for collagen-induced arthritis," J. CLIN. INVEST. 111(5):701-06 (2003)
	AGG	Ogawa et al., "Opposing effects of anti-activation-inducible lymphocyte-immunomodulatory molecule/inducible costimulator antibody on the development of acute versus chronic graft-versus-host disease," J IMMUNOL. 167(10):5741-8 (2001)
	AHH	O'Neill, "Co-stimulating allergy," TRENDS IMMUNOL. 22(4):183 (2001)
	AII	Pound, "A new T-helper cell subset?" Trends Immunol. 22(4):182-3 (2001)
	AJJ	Richter et al., "Tumor necrosis factor- $\alpha$ regulates the expression of inducible costimulator receptor ligand on CD34+ progenitor cells during differentiation into antigen presenting cells," J. OF BIOLOGICAL CHEM. 276(49):45686-45693 (2001)
	AKK	Rottman et al., "The costimulatory molecule ICOS plays an important role in the immunopathogenesis of EAE," NAT IMMUNOL. 2(7):605-11 (2001)
	ALL	Sakamoto et al., "AILIM/ICOS: its expression and functional analysis with monoclonal antibodies," HYBRIDOMA AND HYBRIDOMICS, 20(5):293-303 (2001)
	AMM	Schwartz, "Immunology. It takes more than two to tango," NATURE 409(6816):31-2 (2001)
	ANN	Sperling et al., "ICOS costimulation: It's not just for TH2 cells anymore," NAT IMMUNOL. 2(7):573-4 (2001)
	AOO	Sperling, "ICOS costimulation: is it the key to selective immunotherapy?," CLIN IMMUNOL. 100(3):261-2 (2001)
	APP	Sporici et al., "ICOS ligand costimulation is required for T-cell encephalitogenicity," CLIN IMMUNOL. 100(3):277-88 (2001)
JO	AQQ	Sporici et al., "Costimulation of memory T-cells by ICOS: a potential therapeutic target for autoimmunity?" CLIN IMMUNOL. 100(3):263-9 (2001)

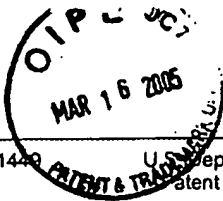
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		Filing Date March 10, 2004	Group Art Unit <del>1645</del> 1644
(37 CFR §1.98(b))			

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JO	ARR	Tamura et al., "B7-H1 costimulation preferentially enhances CD28-independent T-helper cell function," BLOOD 97(6):1809-16 (2001)
J	ASS	Tesciuba et al., "Inducible costimulator regulates Th2-mediated inflammation, but not Th2 differentiation, in a model of allergic airway disease," J IMMUNOL. 167(4):1996-2003 (2001)
JO	ATT	Wallin et al., "Enhancement of CD8+ T cell responses by ICOS/B7h costimulation," J IMMUNOL. 167(1):132-9 (2001)

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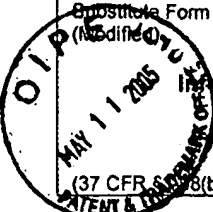
U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
JO	AA	6,451,305	09/17/2002	Boussiotis et al.			

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							Yes	No
JO	AB	2,293,666	12/17/1998	Canada				

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Examiner Initial	Desig. ID	Document

Examiner Signature <i>Lina Ouspenski</i>	Date Considered <i>10/30/2006</i>
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Disclosure Form (PTO-1449)

 Substitute Form PTO-1449 (Modified) U.S. Department of Commerce Patent and Trademark Office <b>Information Disclosure Statement          by Applicant</b> (Use several sheets if necessary) (37 CFR 1.102(b))	Attorney's Docket No. <b>14539-006003</b>	Application No. <b>10/800,250</b>
	Applicant <b>Takashi Tsuji et al.</b>	
	Filing Date <b>March 10, 2004</b>	Group Art Unit <b>1644</b>

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
<i>JD</i>	AA	WO 89/06138 (English language equivalent of RU 2047177)	07/13/1989	WIPO				
<i>JD</i>	AB	WO 94/11499	05/26/1994	WIPO				

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document

Examiner Signature <i>Ilia Orszpewski</i>	Date Considered <i>10/30/2006</i>
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5/12/2006

Sheet 1 of 1

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 14539-006003	Application No. 10/800,250
<b>Information Disclosure Statement by Applicant</b> (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Takashi Tsuji et al.	
		Filing Date March 10, 2004	Group Art Unit 1644

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No

Other Documents (Include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
IO	AA	Chaouat, G. et al., (1995), "IL-10 Prevents Naturally Occuring Fetal Loss in the CBA x DBA/2 Mating Combination, and Local Defect in IL-10 Production in This Abortion-Prone Combination Is Corrected by In Vivo Injection of IFN- $\gamma$ ," <i>J. Immunol.</i> , 154:4261-4268.

Examiner Signature <i>John Oesper</i>	Date Considered 10/30/2006
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

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